

MAY 13 2011

510(k) Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92

Section a):

1. **Submitter:** Aloka Co., Ltd., 10 Fairfield Boulevard, Wallingford, CT 06492

Contact Person: Richard J. Cehovsky, RA/QA Mngr.,
Tel: (203)269-5088 Ext. 346, Fax: 203-269-6075

Date Prepared: 2/17/11
2. **Device Name:** Aloka SSD-3500 Ver. 7.8 Diagnostic Ultrasound System
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90 IYN
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90 ITX
Ultrasonic Pulsed Echo Imaging System., 21 CFR 892.1560, 90 IYO
3. **Marketed Device:** Aloka SSD-3500 Ver. 7.0 Diagnostic Ultrasound System K060059, (90-IYN, ITX, IYO)
(A device currently in commercial distribution)
4. **Device Description:** The SSD-3500 Diagnostic Ultrasound System is a full feature imaging and analysis system. It consist of a mobile console that provides acquisition, processing and display capability. The user interface includes a computer type keyboard, specialized controls and a display.
5. **Indications for Use:** The device is intended for use by a qualified physician for ultrasound evaluation of Small Parts, Abdominal, Cardiac, Peripheral Vascular, Fetal, Intra-operative, Intra-operative (Cardiac), Trans-vaginal, Trans-rectal, Gynecological, Pediatric, Laparoscopic, and Neonatal Cephalic applications.
The device is not indicated for Ophthalmic applications.
6. **Comparison w/ Predicate Device:**
The Aloka SSD-3500 Ver. 7.8 is technically comparable and substantially equivalent to the current Aloka SSD-3500 Ver. 7.0 -(K060059). It has the same technological characteristics, key safety and effectiveness features, and has the same intended uses and basic operating modes as the predicate device.

Section b):

1. **Non-clinical Tests:** The device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform with applicable medical device safety standards.
2. **Clinical Tests:** None Required.
3. **Conclusion:** Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effectiveness performance. Therefore, it is the opinion of Aloka Co., Ltd. that the Aloka SSD-3500 Ver. 7.8 Diagnostic Ultrasound System and its transducers are substantially equivalent with respect to safety and effectiveness to its predicate and other currently cleared Aloka systems.



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Aloka Co., Ltd. (ALOKA AMERICA)
% Mr. Michael S. Ogunleye
510(k) Program Manager/Medical Lead Auditor
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

MAY 13 2011

Re: K111227

Trade/Device Name: Aloka SSD-3500 Ver. 7.8 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: April 24, 2011
Received: May 2, 2011

Dear Mr. Ogunleye:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments; or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aloka SSD-3500 Ver. 7.8 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>UST-533</u>	<u>UST-676P</u>	<u>ASU-1003</u>	<u>UST-5536-7.5</u>
<u>UST-534</u>	<u>UST-677P</u>	<u>ASU-1009</u>	<u>UST-5542</u>
<u>UST-535</u>	<u>UST-978-3.5</u>	<u>UST-5268P-5</u>	<u>UST-5546</u>
<u>UST-536</u>	<u>UST-979-3.5</u>	<u>UST-5293-5</u>	<u>UST-5548</u>
<u>UST-568</u>	<u>UST-984-5</u>	<u>UST-5298</u>	<u>UST-5710-7.5</u>
<u>UST-579T-7.5</u>	<u>UST-987-7.5</u>	<u>UST-5299</u>	<u>UST-9101-7.5</u>
<u>UST-670P-5</u>	<u>UST-990-5</u>	<u>UST-5413</u>	<u>UST-9102-3.5</u>
<u>UST-672-5/7.5</u>	<u>UST-995-7.5</u>	<u>UST-5524-7.5</u>	<u>UST-9102U-3.5</u>

UST-9104-5
UST-9112-5
UST-9121

UST-9123
UST-9124
UST-9127

UST-9128
UST-9133
UST-9136U

UST-MC11-8731

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(K) Number (if known): K111227

Device Name: Aloka SSD-3500 Ver. 7.8

Indications For Use:

The device is intended for use by a qualified physician for ultrasound evaluation of **Small Parts, Abdominal, Cardiac, Peripheral Vascular, Fetal, Intra-operative, Intra-operative (Cardiac), Trans-vaginal, Trans-rectal, Gynecological, Pediatric, Laparoscopic, and Neonatal Cephalic** applications.

The device is not indicated for Ophthalmic applications.


Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Page 1 of 1

510K K111227

1.3.1

Diagnostic Ultrasound Indications for Use Form
SSD-3500 Ver. 7.8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P					See Below	
Intra-operative (specify)		P	P	P					See Below	
Intra-operative (cardiac)		N	N	N					See Below	
Pediatric		P	P	P					See Below	
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic		P	P	P					See Below	
Adult Cephalic										
Cardiac		P	P	P					See Below	
Transesophageal										
Transrectal		P	P	P					See Below	
Transvaginal		P	P	P					See Below	
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P					See Below	
Laparoscopic		P	P	P					See Below	
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes: B/M, B/PWD, M/CD, B/CD/PWD

Applications: Small Parts-(breast, testes & thyroid..), Intra-operative- (liver, pancreas, gall bladder, cardiac....)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)

Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K 15111227

Diagnostic Ultrasound Indications for Use Form

UST-533 (K032875)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P					See Below	
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

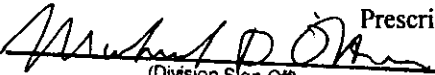
Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD

Applications: Small Parts-(breast, testes & thyroid...), Intra-operative- (liver, pancreas, gall bladder...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K111227

Diagnostic Ultrasound Indications for Use Form
UST-534
(K032875)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		E	E	E					See Below	
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

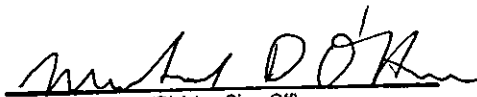
Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Intra-operative- (liver, pancreas, gall bladder,....)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K

15111227

Diagnostic Ultrasound Indications for Use Form
UST- 535
(K042540, K032875))

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intra-operative (specify)		N	N	N					See Below	
Intra-operative (cardiac)		N	N	N					See Below	
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal-										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Intra-operative- (liver, pancreas, gall bladder... & cardiac)

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Prescription Use (Per 21 CFR 801.109)


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Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form**UST-536****(K060059)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P					See Below	
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Applications: Small Parts-(breast, testes & thyroid...), Intra-operative- (liver, pancreas, gall bladder...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111227

Diagnostic Ultrasound Indications for Use Form**UST-568****(K003739)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		E	E	E					See Below	
Pediatric										
Small Organ (specify)		E	E	E					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E					See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

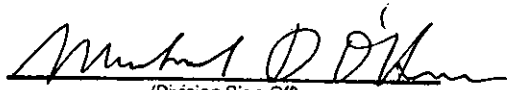
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Applications: Small Parts-(breast, testes & thyroid...), Intra-operative- (liver, pancreas, gall bladder....)
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K

1511227

Diagnostic Ultrasound Indications for Use Form
UST-579T-7.5
(K963616)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P					See Below	
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P					See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E


Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Applications: Small Parts-(breast, testes & thyroid...), Intra-operative- (liver, pancreas, gall bladder...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K111227

Diagnostic Ultrasound Indications for Use Form
UST-670P-5
(K954022)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P					See Below	
Transvaginal		P	P	P					See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

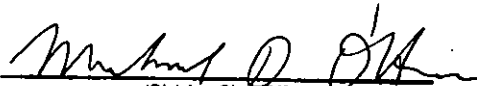
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes- B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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 Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K111227

Diagnostic Ultrasound Indications for Use Form
UST-672-5/7.5
(K992663)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P					See Below	
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

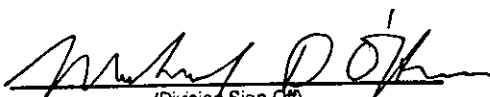
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111227

Diagnostic Ultrasound Indications for Use Form**UST-676P****(K023996)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P					See Below	
Transvaginal		P	P	P					See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

15111227

Diagnostic Ultrasound Indications for Use Form

UST-677P

(K060059)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P					See Below	
Transvaginal		P	P	P					See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

15111227

Diagnostic Ultrasound Indications for Use Form
UST-978-3.5
(K963616)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P					See Below	
Intraoperative (specify)										
Pediatric		P	P	P					See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										


N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form**UST-979-3.5****(K963616)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P						
Abdominal		P	P	P					See Below	
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	


N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K111227

Diagnostic Ultrasound Indications for Use Form

UST-984-5

(K972465)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		P	P	P					See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	

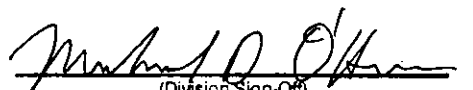
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

UST-987-7.5

(K992663)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P					See Below	
Pediatric										
Small Organ (specify)										
Neonatal Cephalic		P	P	P					See Below	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Intra-operative- (liver, pancreas, gall bladder...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety510K K111227

Diagnostic Ultrasound Indications for Use Form
UST-990-5
(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	
Abdominal		P	P	P					See Below	
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac- Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	

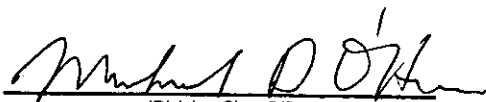
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)

Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111227

Diagnostic Ultrasound Indications for Use Form

UST-995-7.5

(K992663)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P					See Below	
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P					See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

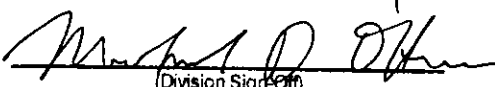
Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Intra-operative- (liver, pancreas, gall bladder...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form**ASU-1003****(K020668)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Pediatric)										
Transesophageal										
Transrectal										
Transvaginal		P	P	P					See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	

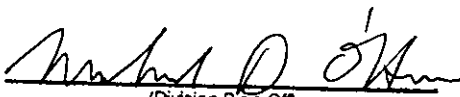
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

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1511027

Diagnostic Ultrasound Indications for Use Form

ASU-1009

(K060059)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal		P	P	P					See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

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K111227

Diagnostic Ultrasound Indications for Use Form
UST-5268P-5
(K992663)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intra-operative (specify)		P	P	P					See Below	
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E


Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Intra-operative application: (liver, pancreas, gall bladder...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

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15111227

Diagnostic Ultrasound Indications for Use Form**UST-5293-5****(K003739)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P					See Below	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

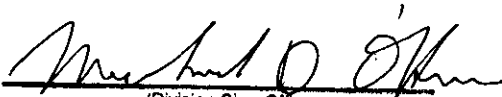
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form**UST-5298****(K003739)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric		P	P	P					See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P					See Below	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

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K111227

Diagnostic Ultrasound Indications for Use Form

UST-5299

(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P					See Below	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										


N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

UST-5413

(K992663)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P					See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Small Parts-(breast, testes & thyroid..),

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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K111227

Diagnostic Ultrasound Indications for Use Form
UST-5524-7.5
(K963616)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P					See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Small Parts-(breast, testes & thyroid..),

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

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1111227

Diagnostic Ultrasound Indications for Use Form
UST-5536-7.5
(K992663)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P					See Below	
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic		P	P	P					See Below	
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

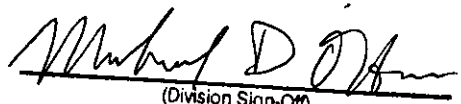
Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Intra-operative- (liver, pancreas, gall bladder...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

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K111227

Diagnostic Ultrasound Indications for Use Form**UST-5542****(K003739)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P					See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Small Parts-(breast, testes & thyroid..),

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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K111227

Diagnostic Ultrasound Indications for Use Form**UST-5546****(K023996)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P					See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Small Parts-(breast, testes & thyroid..),

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K111227

Diagnostic Ultrasound Indications for Use Form

UST-5548

(K032875)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P					See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Small Parts-(breast, testes & thyroid..),

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form
UST-5710-7.5
(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E


Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Small Parts-(breast, testes & thyroid..),

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111227

Diagnostic Ultrasound Indications for Use Form

UST-9101-7.5

(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal			P	P	P				See Below	
Intraoperative (specify)										
Pediatric			P	P	P				See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

OK

K111227

Diagnostic Ultrasound Indications for Use Form**UST-9102-3.5****(K012253)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P					See Below	
Intraoperative (specify)										
Pediatric		P	P	P					See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										


N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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510K K011227

Diagnostic Ultrasound Indications for Use Form
UST-9102U-3.5
(K012253)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P					See Below	
Intraoperative (specify)										
Pediatric		P	P	P					See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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K111227

Diagnostic Ultrasound Indications for Use Form**UST-9104-5****(K003739)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P					See Below	
Pediatric										
Small Organ (specify)										
Neonatal Cephalic		P	P	P					See Below	
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Intra-operative- (liver, pancreas, gall bladder...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



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K111227

Diagnostic Ultrasound Indications for Use Form

UST-9112-5

(K012253)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal		P	P	P					See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



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K111227

Diagnostic Ultrasound Indications for Use Form

UST-9121

(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P					See Below	
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



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K111227

Diagnostic Ultrasound Indications for Use Form

UST-9123

(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	
Abdominal		P	P	P					See Below	
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	


N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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K111227

Diagnostic Ultrasound Indications for Use Form

UST-9124

(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal		P	P	P					See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



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K111227

Diagnostic Ultrasound Indications for Use Form

UST-9127

(K060059)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	
Abdominal		P	P	P					See Below	
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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K111227

Diagnostic Ultrasound Indications for Use Form

UST-9128

(K032875)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal		P	P	P					See Below	
Intraoperative (specify)										
Pediatric		P	P	P					See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Prescription Use (Per 21 CFR 801.109)



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K111227

Diagnostic Ultrasound Indications for Use Form**UST-9133****(K060059)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P					See Below	
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Intra-operative- (liver, pancreas, gall bladder...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



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K111232

Diagnostic Ultrasound Indications for Use Form**UST-9136U****(K043196)**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		E	E	E					See Below	
Abdominal		E	E	E					See Below	
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		E	E	E					See Below	

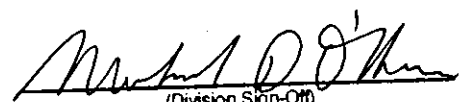
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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 Office of In Vitro Diagnostic Device Evaluation and Safety

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K111227

Diagnostic Ultrasound Indications for Use Form
UST-MC11-8731
(K032875)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P					See Below	
Pediatric										
Small Organ (specify)		P	P	P					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Neonatal)										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P					See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E


Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD.

Applications: Small Parts-(breast, testes & thyroid...), Intra-operative- (liver, pancreas, gall bladder...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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